K073070

510(K) SUMMARY
DIO Biotite-H Implant Systems

MAY 16 2008

15-1. Submitter	DIO Department, DSI, Inc. 117 Kyo-Dong, Yangsan-City Kyungnam-Do, 626-210, South Korea Phone: 82-55-363-3401 Fax : 82-55-363-3404
15-2. US Agent / Contact Person	PhD. Steve Chang 13340 E. Firestone Blvd. Suite J Santa Fe Springs, CA 90670 Phone : 562-404-8466, Fax : 562-404-2757
15-3. Date Prepared	October 26, 2007
15-4. Device Name	DIO BIOTITE-H IMPLANT SYSTEMS
15-5. Classification Name	Endosseous Dental Implant System
15-6. Device Classification	Class II Dental Devices panel 21 CFR ξ 872.3640 Regulation Number:
15-7. Predicate Devices	IMPLANT INOVATION, INC. (K 955428)
15-8. Performance	Laboratory testing was conducted to determine device functionality and conformance to design input requirements.

15-9. Device Description

The DIO Biotite-H Implant System is comprised of dental implant, surgical instruments and prosthetic components. The DIO BIOTITE –H Implant System is designed for conventional two-stage procedures for single and multiple unit prosthetics. The DIO Biotite-H Implant System's screw-form dental implant consist of machined titanium. Screw's Diameter: Ø 3.8mm, Ø 4.1mm, Ø 4.5mm, Ø 4.8mm, Ø 5.3mm. Length: 8.0mm, 10.mm, 12.0mm, 14.0mm. The implant's raw material is titanium and its alloys for surgical implant applications (as perASTM-F-67, A~STM-F-136). The special implant surface is consists of 100% calcium phosphate($CaHPO_4 2H_2O$). BioTite-H Implant System is an electrochemically deposited calcium phosphate coating based upon a biomimetic process in which implants are coated in an electrolytic bath with a 15+/- 5μm thin bioactive layer of a calcium phosphate composite. Biotite –H Implant System composed of the two calciumphosphates brushite(>95%)and HA(<5%).

15-10. Packing / Labeling / Product Information

In a clean room that is Class 10,000 or less, put the product into a capsule, and then put the capsule in a pet container, which is 45mm by 75mm, then sealed the pet container with PERFECSEAL CR27 1073B Coated Tyvek®. DIO Biotite-H Implant Systems DIO Biotite –H Implant Fixtures will be packaged.

15-11. Intended Use

The DIO Biotite-H Implant System is an endosseous dental implant that is indicated to use for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple units' prosthetic appliance attachment to restore a patient's chewing function. Also, angled abutments on small diameter implants (3.8mm) of the DIO Biotite-H Implant System are intended for the anterior region of the mouth and not intended for the posterior region of the mount due to possible failure of the implant.

15-12. Substantial Equivalence Comparison

The following are the predicate devices that are substantially equivalent to the Calcium Hydroxylapatite Implant:

K955428	Implant Innovation, Inc. 3i Hydroxylapatite Coated Standard Thread
K940348	OsteoGraft/D-700 CeraMed Corporation. 12860 West cedar Drive. Lakewood, Co 80228
K882682	alcitie Calcitek, Inc., 4125-B Sorrento Valley Boulevard, San Diego, CA 92121
K852742	Osteograf AR Alveolar Ridge Hydroxylapatite 18-40 Coors Biomedical Company, 12860 West Cedar Drive, Lakewood, CO 80228
K852765	HA-2000 Orthomatrix, Inc., 6968 Sierra Court, Dublin CA 94568
K992416	Perioglas-BioGlass Bone Graft Particulate U.S. Biomaterials Corp., One Progress Boulevard, Alachua, FL 32615
K000149	Novabone-Bioglass Bone Graft Particulate U.S. Biomaterials Corp., One Progress Boulevard, Alachua, FL 32615
K952922	Biogran Bioactive Glass Synthetic Bone Graft Material Orthovita Co., 212 Carnegie Center Drive, Suite 206, Princeton, NJ 08540
K921468	PermanMesh Hydroxylapatite Matrix CeraMed Corp., 12860 West Cedar Drive, Lakewood, CO 80228
K862061	Osteograf/AR+Permaridge Hydroxylapatite, 18-40 Coors Biomedical Company, 12860 West Cedar Drive, Lakewood, CO 80228
K910432	HAPSET Hydroxylapatite Bone Graft Plaster Lifecore Biomedical, Inc., 1050 Connecticut Avenue, N.W. Washington Square, Suite 1100, Washington, D.C. 20036

The Biotite-H Implant is substantially equivalent to the predicate device sited above.

TECHNOLOGICAL CHARACTERISTIC COMPARISON

	Subject Device	Predicate Device
Device Name	DIO DENTAL IMPLANT CO. LTD (DIO Biotite-H Implant System)	IMPLANT INOVATION, INC. (K 955428)
Intended Use	Identical to predicate devices	The implants are indicated for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment in single tooth restoration and in partially or fully edentulous spans with multiple single teeth, or as a terminal or intermediary abutment for fixed or removable bridgework, and to retain overdentures.
Material	Commercially pure titanium GR. 3 and GR.4 (ASTM-F-67)	Commercially pure titanium Gr. 3 and Gr.4 (ASTM-F-67)
Design	Morse Taper with Thread	Morse Taper with Thread
Screw Threads	YES	YES
Implant Thread Diameter (mm)	3.8, 4.1, 4.5, 4.8 and 5.3 mm	3.8, 4.5, and 5.3 mm
Collar Height (mm)	1.8	1.8
Lengths (External)	8-14 mm	8-14 mm
Surface Treatment	HA Coating	HA Coating
Gamma sterilized	YES	YES

Attachments

Screw-retained restoration system	YES	YES
Cemented restoration system	YES	YES
Overdenture restoration	YES	YES
Instruments (surgical and restorative)	YES	YES

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR & 807.93

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DIO Department, DSI, Incorporated
C/O Dr. Steve Chang
Kodent, Incorporated
13340 East Firestone Boulevard, Suite J
Santa Fe Springs, California 90670

MAY 16 2008

Re: K073070
Trade/Device Name: DIO Biotite-H Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: May 14, 2008
Received: May 16, 2008

Dear Dr. Chang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

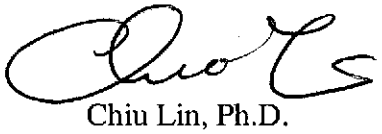
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(K) Number (if known): K073070

Device Name: DIO Biotite-H Implant System

Indications For Use:

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Tam Mulay for MSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K073070

Prescription Use X AND/OR _____ Over – The-Counter Use
(Part 21 CFR 801 Subpart D) (Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)